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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,240	03/23/2004	Giovanni Caponetti	250893US0CONT	1764

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,240	CAPONETTI ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/030,686.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/22/04;3/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 22-33 are pending. The previous office action, mailed on June 28, 2006 **is vacated**, because the incorrect claim set was examined.

Information Disclosure Statement

Receipt of the IDS's submitted on September 22,2004 and March 23, 2004 is acknowledged. The last page of the IDS filed on 9/22/04 was not a proper PTO-1449 form and was not considered.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks PULVINAL® (pg. 22, line 25; pg. 23, line 10; and pg. 26, line 19) and TURBULA® (pg. 22, lines 11 and 18; Example 5 on pg. 29) have been noted in this application. Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is vague and indefinite because the term "substantially free" is ambiguous as to its intended metes and bounds and said term is not defined in the instant specification.

Claim 27 is vague and indefinite, because it is unclear whether "(impeller)" is intended as another claim limitation or whether it is merely recites a synonym for the term "rotating paddle."

Claim 28 is vague and indefinite because

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-26 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Ganderton et al. (U.S. Patent No. 5,376,386).

Applicant claims a process of making carrier particles with a median diameter greater than 90 microns and a surface rugosity ≤ 1.1, comprising the step of subjecting the plurality of particles to repeated stages of wetting of a solvent and drying.

Ganderton discloses aerosol carriers in which the average size of the particles of the carrier is preferably in the range **5 to 1,000 microns** and most preferably 50 to 100 microns and

having a rugosity of less than 1.75 (title, abstract, col. 2, lines 16-19). Size reads on diameter. A rugosity of less than 1.75 encompasses Applicants' claimed range. The carrier particles disclosed by Ganderton are recrystallized from an aqueous solution (col. 2, lines 23-26). The preferred carrier materials include monosaccharides such as fructose, **mannitol**, arabinose, xylitol and dextrose (glucose) and their monohydrates, disaccharides such as **lactose, maltose**, or sucrose and polysaccharides such as starches, **dextrins** or dextrans, with crystalline carriers having a low affinity for water, including **lactose**, being especially preferred (col. 2, lines 5-15). Specifically, the solvent mixtures may be briskly agitated throughout the period of crystallization and crystal growth. After the crystal growth phase the particles may be recovered by filtration and are usually washed, e.g. with the miscible solvent to remove excess mother liquor prior to drying. The particles may be subject to further washes, e.g. with ethanol and ethanol/water mixtures to improve the purity. These washes also serve to reduce the quantities of very fine particles present in the product, which may be preferable (col. 3, lines 8-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganderton et al. (U.S. Patent No. 5,376,386) in view of Kato et al. (EP 0786526; IDS).

Applicant Claims

Applicant claims a method for the preparation of carrier particles comprising carrying out repeated stages of wetting and drying in a high-speed granulator consisting of a cylindrical mixing chamber comprising a rotating paddle and a sprayer (claim 27), such as a Roto J Zanchetta or Diosna apparatus (claim 28), wherein the total mixing time during the repeated wetting and drying stages ranges from 120-300 minutes (claims, 29 and 33), and the solvent is a water/alcohol mixture from 9:3 to 3:4 v/v (claims 30-31).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Ganderton have been set forth above. Kato teaches lactose spherical particles and processes for their production comprising a step of **charging crystalline lactose and/or lactose granules onto a rotary disk** in the **treatment vessel** (i.e. container) of a centrifugal tumbling apparatus, dispersing powdered lactose to the lactose granules and/or crystalline lactose as the rotary disk is rotated while providing slit air into the vessel, **while also spraying water, an aqueous lactose solution or a dilute aqueous solution of a water-soluble polymer**, and a fixation treatment step of drying the obtained spherical particles in a fluidized bed apparatus while spraying an aqueous lactose solution and/or a dilute solution of a water-soluble polymer (title and abstract). The crystalline lactose serving as the nuclei according to the invention is crystalline lactose, preferably with a **particle size between 150 microns and 300 microns** (col. 3, lines 50-53). The lactose particles preferably have a preferred abrasiveness no greater than 1.0%, most preferably no greater than 0.5% (col. 5, lines 1-3). Abrasiveness reads on roughness and rugosity. The production of the lactose particles of Kato's invention may be practiced using a CF granulator, depicted in Figure 1, and comprising a granulation vessel (i.e. container), spray nozzle, rotary disk, etc (Figure 1 and col. 11, lines 5-24). A rotary disk reads on a rotating paddle.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Ganderton lacks the teaching of a method of producing smooth carrier particles utilizing a granulator and compositions comprising specific ethanol/water mixtures. These deficiencies are cured by the teachings of Kato and what is commonly known in the art.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Ganderton and Kato, because Ganderton teaches dry powder medicinal compositions comprising particles of a saccharide carrier (e.g. lactose) and Kato teaches a method of producing smooth lactose carrier particles utilizing a granulator. A skilled artisan would have been motivated to combine the teachings of Ganderton and Kato, because Kato's disclosed method and granulator would have provided the artisan with a suitable method and device for the preparation of Ganderton's compositions, also comprising a carrier. For these reasons, a skilled artisan would have had a reasonable expectation of success upon combing the teachings of the prior art. The use of ethanol/water mixtures in spray driving is a well-known conventional practice in the art (See for example, (1) Osborne et al. USPN 5,741,478; Example 1 [especially col. 9, lines 56-62] and (2) Edwards et al. USPN 5,985,309; Examples 5-6). It is known in the art to modify the ratio of ethanol to water based upon the solubility of the components of a formulation. Regarding the specific commercially available high-speed granulators cited in claim 28, it would have been obvious to a skilled artisan to use commercially available granulators, because these are readily available to the skilled artisan, are known to be used in the art for the preparation of particulate compositions, and are very similar to other high-speed granulators (See, for example, (1) Vojnovic, D. et al. "Optimization of Granulates in a High Shear Mixer by Mixture Design," *Drug Development and Industrial Pharmacy*, **1994**, *20(6),* pp1035-1047; (2) Vojnovic, D. et al. "Simultaneous Optimization of Several Response Variables in a Granulation Process," *Drug Development and Industrial*

Pharmacy, **1993**, *19(12),* 1479-1496; or (3) Vojnovic, D. et al. "Wet Granulation in a Small Scale High Shear Mixer," *Drug Development and Industrial Pharmacy*, **1992**, *18(9),* 961-972).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-29 and 32-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,780,508 (USPN '508). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of USPN '508 are obvious over the claims of the instant application, because they collectively have the same limitations. Both claim sets recite carriers coated with an additive, having a median diameter greater than 90 microns and a rugosity that is less than or equal to 1.1. Additionally, both claim sets recite the same Markush groups of water-

soluble polymers, additives, lubricants, and anti-adherents. Both claim sets also recite processes of making a carrier characterized by a median diameter of greater than 90microns and a surface rugosity of less than or equal to 1.1 (claim 9 in USPN '508 and claim 22 in the instant application). The citation of specific commercially available high-speed granulators in claim 28 of the instant application is obvious over the disclosure in claim 9 of USPN '508 of a process utilizing a high-speed granulator. The claimed surface rugosity range of 1.0-1.1 (claims 24 and 32 of the instant application) are obviated by the limitation of a surface rugosity equal to or less than 1.1 in claim 9 of the USPN '508, because this overlaps with Applicants' claimed range. Therefore, claims 22-29 and 32-33 are *prima facie* obvious over the cited claims of USPN '508.

Other Matter

The Examiner respectfully suggests insertion of the U.S. Patent number of the instant application's parent in the first line of the specification.

Conclusion

Claims 22-33 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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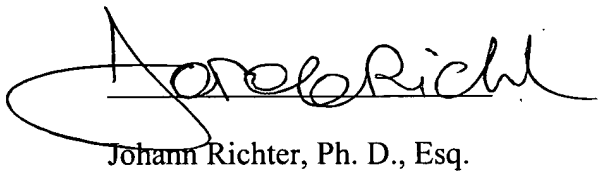

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